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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,884	10/23/2000	Kiyozo Asada	1422-443P	6983

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EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
	1637

DATE MAILED: 09/22/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/673,884	ASADA ET AL.
	Examiner	Art Unit
	Jeffrey Siew	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 July 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9, 16-18, 21-23 and 31-35 is/are pending in the application.

4a) Of the above claim(s) 35 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9, 16-18, 21-23 and 31-34 is/are rejected.

7) Claim(s) 35 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> .	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY THE AMENDMENT

Claim Objections

1. Claim 35 is objected to under 37 CFR 1.75(c) as being in improper form because the claim refers to two sets of claims of different features. See MPEP § 608.01(n). Accordingly, the claim 35 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3-9,16-18,21-23,31-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claim recites “acid macromolecular substances that do not serve as templates”. The claim covers a wide genus of diverse and complex species. The specification discloses only a minimal number of chemical species. Given the dearth of species

as compared to the broad and varying species that the claim covers, the specification fails to describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Blakely et al (US5,418,162 May 23, 1995).

Blakely teach heparin sulfate which prevents non specific hybridization (see col. 16 line 26).

Applicant is reminded that further limitations on one of the alternatives in the parent claim does not necessarily prevent the reading of the claim on the other alternative claims (see particularly claim 5-9).

4. Claims 1,3-9, 16,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chetverin et al (US5,616,478 April 1, 1997)

Chetverin teach carrageenan, alginate and particularly polyacrylamide in the PCR and compositions comprising such chemicals in amplification (see whole doc. esp col. 7 line 1 –39). They teach the addition of DNA polymerases and acrylamide (see example 3)

5. Claims 1,3,4, 16-18, 21,22 & 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Koster et al (US5,928,906 July 27, 1999).

Koster teach amplification with two polymerases such as Pfu which is alpha type and Vent polymerases which is non alpha type polymerase. They teach the addition of cation Mg 2+ to enhance the reaction (see e.g. col. 12 line 32).

6. Claims 1, 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Barton (US5,225,556 July 6, 1993).

Barton teach rhodium metal complex (see whole doc. esp. abstract). The term DNA synthesis enhancer may reasonably interpreted as intended use and may read on any rhodium metal complex.

7. Claims 1, 3,416-18,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorge et al (US5,556,772 Sept, 17, 1996).

Sorge et al teach two polymerase mixture one containing Pfu in which one enzyme has 3'-5' exonuclease activity and the other Taq which substantially has no 3'-5' activity (see whole doc esp abstract). They teach cations e.g. Mg²⁺ in the reaction buffer (see Table 17).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chetverin et al (US5,616,478 April 1, 1997) in view of Sorge et al (US5,556,772 Sept, 17, 1996).

The teachings of Chetverin et al are described previously.

Chetverin et al do not teach two polymerases

Sorge et al teach two polymerase mixture one containing Pfu in which one enzyme has 3'-5' exonuclease activity and the other Taq which substantially has no 3'-5' activity (see whole doc esp abstract).

One of ordinary skill in the art would have been motivated to apply Sorge et al's two polymerase mixture to Chetverin et al's amplification method in order to amplify the target DNA. Sorge states that the polymerase mixture allows for increased product yield and synthesis and allows polynucleotide cannot be synthesized by any given polymerase alone (see col. 3 line 22-25). It would have been prima facie obvious to apply Sorge et al's mixture to Chetverin et al's method in order to increase product yield.

9. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorge et al (US5,556,772 Sept, 17, 1996) in view of Gaugler et al (US5,512,437 April 30, 1996).

Sorge et al teach two polymerase mixture one containing Pfu in which one enzyme has 3'-5' exonuclease activity and the other Taq which substantially has no 3'-5' activity (see whole doc esp abstract). They teach cations e.g. Mg²⁺ in the reaction buffer (see Table 17).

Sorge et al do not teach a kit.

Gaugler et al teach a kit for PCR containing reagents such as polymerase (see col.6 line 35-38).

One of ordinary skill in the art would have applied Gaugler et al's teaching of a kit to Sorge et al's polymerases in order to efficiently perform PCR. It was well known and commonly

practiced in the art to incorporate reagents of an assay within one kit. It would have been *prima facie* obvious to apply Gaugler et al's teaching of kit to incorporate Sorge et al's polymerases into a single kit in order for the practitioner to have easy access to the PCR reagents and perform the assay efficiently.

SUMMARY

10. No claims allowed.

CONCLUSION

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER

September 15, 2003